

APPLICATION NO.	FILING DATE
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09/492,392 01/27/00

COMMERCIAL



DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
NUMBER OF PATENTS AND TRADEMARKS  
20231

HM22/0626

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ATTORNEY DOCKET NO.  
03806-0464

MINER

165

DATE MAILED:

Oct 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/492,392</b>	Applicant(s) <b>Commercon</b>
	Examiner <b>David Lukton</b>	Art Unit <b>1653</b>



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1)  Responsive to communication(s) filed on May 29, 2001

2a)  This action is FINAL.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1835 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

4)  Claim(s) 17-33 is/are pending in the applica

4a) Of the above, claim(s) 25-31 and 33 is/are withdrawn from considera

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 17-24 and 32 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirem

#### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

15)  Notice of References Cited (PTO-892)

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20)  Other: \_\_\_\_\_

Pursuant to the directives of paper No. 9 (filed 5/29/01), claims 1-16 have been cancelled, and claims 17-33 added. Claims 17-33 are pending.

Applicants' election of Group I with traverse is acknowledged, as is the elected specie. Claims 25-31 and 33 are withdrawn from consideration; claims 17-24 and 32 are examined in this Office action.

Applicants have argued that the non-elected claims should be rejoined. As indicated in the previous Office action, in the event that Group I compounds are determined to be allowable, novelty will accrue to the non-elected claims, and rejoining them would be appropriate. However, even if the non-elected claims were rejoined at this time, they would not be allowable either; so the point is moot, at least now. The restriction is maintained at the present time.

\*

**An abstract is required,** and does not appear to have been submitted.

\*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-24 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have asserted that the claimed compounds are effective to inhibit growth of bacteria, yet there is no evidence that this is the case. The reality in pharmacology is that one cannot predict activity merely by viewing a structure. It may be the case that the claimed compounds are analogous to other compounds which have been shown to inhibit bacterial growth. However, even small changes in structure can lead to dramatic changes in activity, or obliteration of activity.

It is suggested that applicants provide at least *in vitro* data that establishes the bacterial growth inhibitory efficacy that has been asserted; also suggested is that the terms "pharmaceutical" and "pharmaceutically" be deleted from whichever claims recite them. These latter terms imply therapeutic efficacy, which is not in evidence.

\*

Claims 17-24 and 32 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 makes reference to "R" and "S" epimers, without identifying which carbon is at issue. Presumably it is the carbon bearing R<sub>1</sub>.

Claim 17 is drawn to a compound, i.e., one compound. However, at the end of the claim, reference is made to mixtures of compounds. It is suggested that a separate claim be

created for the mixtures, and that the end of claim 17 be amended to recite the following:

*when R" is hydrogen, alkyl, cycloalkyl, allyl, propynyl, or benzyl, the carbon bearing R, is of the R configuration; and*

*when R" is OR''' or N(R<sub>3</sub>)R<sub>4</sub>, the carbon bearing R, is of the R configuration or the S configuration.*

A claim such as the following could also be created:

*34. A mixture consisting of a first compound of formula I and a second compound of formula I*

....

*wherein the first compound, the carbon bearing R, is of the R configuration, and*

*wherein the second compound, the carbon bearing R, is of the S configuration, and*

*when R" is hydrogen, alkyl, cycloalkyl, allyl, propynyl, or benzyl, the molar ratio of the first compound to the second compound is greater than 1.0.*

A simpler, though less desirable option would be to amend claim 17 to make it clear that compounds, salts and mixtures of stereoisomers of the compounds are being claimed.



DAVID LUKTON  
PATENT EXAMINER  
GROUP 1800

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.